IN THE CLAIMS

1. (Original) A crystalline form of dextrorotatory dihydrochloride salt of [2-[4-[(4-chlorophenyl)-phenyl methyl]-1-piperazinyl] ethoxy] acetic acid (dextrorotatory dihydrochloride salt of cetirizine).

2. (Original) A crystalline form of a dextrorotatory dihydrochloride salt of cetirizine having substantially the same X-ray diffraction pattern as shown in FIG. 1.

3. (Original) A crystalline form of dextrorotatory dihydrochloride salt of cetirizine having an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer equipped with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 7.05 ± 0.09, 7.96 ± 0.09, 14.35 ± 0.09, 14.81 ± 0.09, 17.40 ± 0.09, 18.17 ± 0.09, 18.59 ± 0.09, 18.82 ± 0.09, 20.33 ± 0.09, 22.33 ± 0.09, 23.35 ± 0.09, 24.16 ± 0.09, 24.33 ± 0.09, 24.73 ± 0.09, 25.28 ± 0.09, 26.51 ± 0.09, 26.80 ± 0.09, 27.35 ± 0.09 and 30.57 ± 0.09.

4. (Original) The crystalline form of dextrorotatory dihydrochloride salt of cetirizine of claim 1, that has an endo-endo pattern with identified peaks of about 195°C and 215°C in its differential scanning colorimetry thermogram.

5. (Original) The crystalline form of dextrorotatory dihydrochloride salt of cetirizine of claim 1, having an infrared spectrum with identifiable peaks at about 3430, 2949, 2376, 1746, 1497, 1320, 1137, 920, 759, 720, 700 and 534 cm^{-1}.

6. (Original) A pharmaceutical composition comprising a prophylactically or therapeutically effective amount of the crystalline form of dextrorotatory dihydrochloride salt of cetirizine of claim 1 and one or more pharmaceutically acceptable excipients.

7. (Original) The pharmaceutical composition of claim 6, wherein said crystalline form of dextrorotatory dihydrochloride salt of cetirizine has an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 7.05 ± 0.09, 7.96 ± 0.09, 14.35 ± 0.09, 14.81 ± 0.09, 17.40 ± 0.09, 18.17 ± 0.09, 18.59 ± 0.09, 18.82 ± 0.09, 20.33 ± 0.09, 22.33 ± 0.09, 23.35 ± 0.09, 24.16 ± 0.09, 24.33 ± 0.09, 24.73 ± 0.09, 25.28 ± 0.09, 26.51 ± 0.09, 26.80 ± 0.09, 27.35 ± 0.09, and 30.57 0.09.

8. (Original) A process for preparation of a crystalline form of dextrorotatory dihydrochloride salt of cetirizine, said process comprising:

a) providing a solution of dextrorotatory dihydrochloride salt of cetirizine in a ketone-containing solvent;

b) cooling said solution thereby a solid separates; and

c) isolating said solid mass thereby obtaining said crystalline form of dextrorotatory dihydrochloride salt of cetirizine.

9. (Original) The process according to claim 8, wherein said ketone-containing solvent comprises water and a ketone selected from the group consisting of acetone, methyl ethyl ketone, dimethyl ketone, 2-pentanone, and mixtures thereof.

10. (Original) The process according to claim 9, wherein said ketone-containing solvent

comprises water and acetone.

11. (Original) The process according to claim 9, which further comprises drying said isolated solid mass at from about 40°C to about 100°C.

12. (Original) The process according to claim 11, wherein said isolated mass is dried at from about 55°C to about 65°C.

13. (Original) A crystalline form of dextrorotatory dihydrochloride salt of cetirizine produced in accordance with the process of claim 8.

14. (Original) The crystalline form of dextrorotatory dihydrochloride salt of cetirizine of claim 13 and having an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer equipped with a diffracted beam curved graphite monochromator using copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 7.05 ± 0.09, 7.96 ± 0.09, 14.35 ± 0.09, 14.81 ± 0.09, 17.40 ± 0.09, 18.17 ± 0.09, 18.59 ± 0.09, 18.82 ± 0.09, 20.33 ± 0.09, 22.33 ± 0.09, 23.35 ± 0.09, 24.16 ± 0.09, 24.33 ± 0.09, 24.73 ± 0.09, 25.28 ± 0.09, 26.51 ± 0.09, 26.80 ± 0.09, 27.350.09 and 30.57 ± 0.09.

15. (Original) A pharmaceutical composition comprising a) a prophylactically or therapeutically effective amount of the crystalline form of dextrorotatory dihydrochloride salt of cetirizine produced by the process of claim 8 and b) one or more pharmaceutically acceptable excipients.

16. (Original) A pharmaceutical composition comprising a) a prophylactically or

therapeutically effective amount of the crystalline form of dextrorotatory dihydrochloride salt of cetirizine produced by the process of claim 8 and having an X-ray diffraction pattern expressed in terms 2 theta angles and obtained with a diffractometer equipped with a diffracted beam curved graphite monochromator using copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 7.05 ± 0.09, 7.96 ± 0.09, 14.35 ± 0.09, 14.81 ± 0.09, 17.40 ± 0.09, 18.17 ± 0.09, 18.59 ± 0.09, 18.82 ± 0.09, 20.33 ± 0.09, 22.33 ± 0.09, 23.35 ± 0.09, 24.16 ± 0.09, 24.33 ± 0.09, 24.73 ± 0.09, 25.28 ± 0.09, 26.51 ± 0.09, 26.80 ± 0.09, 27.35 ± 0.09, and 30.57 ± 0.09, and b) one or more pharmaceutically acceptable excipients.

17. (Original) A crystalline form of levorotatory dihydrochloride salt of [2-[4-[(4-Chlorophenyl)-phenyl methyl]-1-piperazinyl] ethoxy] acetic acid (levorotatory dihydrochloride salt of cetirizine).

18. (Original) A crystalline form of a levorotatory dihydrochloride salt of cetirizine having substantially the same X-ray diffraction pattern as shown in FIG. 2.

19. (Original) A crystalline form of levorotatory dihydrochloride salt of cetirizine having an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer equipped with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 7.10 ± 0.09, 8.02 ± 0.09, 14.41 ± 0.09, 14.87 ± 0.09, 17.48 ± 0.09, 18.24 ± 0.09, 18.65 ± 0.09, 18.86 ± 0.09, 22.39 ± 0.09, 23.42 ± 0.09, 24.21 ± 0.09, 24.36 ± 0.09, 24.81 ± 0.09, 25.31 ± 0.09, 26.60 ± 0.09 and 29.28 ± 0.09.

20. (Original) The crystalline form of levorotatory dihydrochloride salt of cetirizine of claim 17 that has an endo-endo pattern with identified peaks of about 195°C and 215°C in its differential scanning colorimetry thermogram.

21. (Original) The crystalline form of levorotatory dihydrochloride salt of cetirizine of claim 17 having an infrared spectrum with identifiable peaks at about 3430, 2949, 2376, 1746, 1497, 1320, 1137, 920, 759, 720, 700 and 534 cm^{-1}.

22. (Original) A pharmaceutical composition comprising a prophylactically or therapeutically effective amount of the crystalline form of levorotatory dihydrochloride salt of cetirizine of claim 17, and one or more pharmaceutically acceptable excipients.

23. (Original) The pharmaceutical composition of claim 22, wherein said crystalline form of levorotatory dihydrochloride salt of cetirizine has an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 7.10 ± 0.09, 8.02 ± 0.09, 14.41 ± 0.09, 14.87 ± 0.09, 17.48 ± 0.09, 18.24 ± 0.09, 18.65 ± 0.09, 18.86 ± 0.09, 22.39 ± 0.09, 23.42 ± 0.09, 24.21 ± 0.09, 24.36 ± 0.09, 24.81 ± 0.09, 25.31 ± 0.09, 26.60 ± 0.09 and 29.28 ± 0.09.

24. (Original) A process for preparation of a crystalline form of levorotatory dihydrochloride salt of cetirizine, said process comprising:

a) providing a solution of levorotatory dihydrochloride salt of cetirizine in a ketone-containing solvent;

b) cooling said solution thereby a solid separates; and

c) isolating said solid mass thereby obtaining said crystalline form of

levorotatory dihydrochloride salt of cetirizine.

25. (Original) The process according to claim 24, wherein said ketone-containing solvent comprises water and a ketone selected from the group consisting of acetone, methyl ethyl ketone, dimethyl ketone, 2-pentanone, and mixtures thereof.

26. (Original) The process according to claim 25, wherein said ketone-containing solvent comprises water and acetone.

27. (Original) The process according to claim 24, which further comprises drying said isolated solid mass at from about 40°C to about 100°C.

28. (Original) The process according to claim 24, wherein said isolated solid mass is dried at from about 55°C to about 65°C.

29. (Original) The crystalline form of levorotatory dihydrochloride salt of cetirizine produced in accordance with a process of claim 24.

30. (Original) The crystalline form of levorotatory dihydrochloride salt of cetirizine of claim 29 and having an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer equipped with a diffracted beam curved graphite monochromator using copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 7.10 ± 0.09, 8.02 ± 0.09, 14.41 ± 0.09, 14.87 ± 0.09, 17.48 ± 0.09, 18.24 ± 0.09, 18.65 ± 0.09, 18.86 ± 0.09, 22.39 ± 0.09, 23.42 ± 0.09, 24.21 ± 0.09, 24.36 ± 0.09, 24.81 ± 0.09, 25.31 ± 0.09, 26.60 ± 0.09 and 29.28 ± 0.09.

31. (Original) A pharmaceutical composition comprising a) a prophylactically or therapeutically effective amount of the crystalline form of levorotatory dihydrochloride salt of cetirizine produced by the process of claim 24 and b) one or more pharmaceutically acceptable excipients.

32. (Original) A pharmaceutical composition comprising a) a prophylactically or therapeutically effective amount of the crystalline form of levorotatory dihydrochloride salt of cetirizine produced by the process of claim 24 and having an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer equipped with a diffracted beam curved graphite monochromator using copper K X-radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of 7.10 ± 0.09, 8.02 ± 0.09, 14.41 ± 0.09, 14.87 ± 0.09, 17.48 ± 0.09, 18.24 ± 0.09, 18.65 ± 0.09, 18.86 ± 0.09, 22.39 ± 0.09, 23.42 ± 0.09, 24.21 ± 0.09, 24.36 ± 0.09, 24.81 ± 0.09, 25.31 ± 0.09, 26.60 ± 0.09 and 29.28 ± 0.09.

33. (Currently amended) The pharmaceutical composition of claim 16 ~~or 32~~, which is a solid dosage form for oral administration.

34. (Original) The pharmaceutical composition of claim 33, wherein said solid dosage form is a tablet.

35. (Original) An amorphous form of dextrorotatory dihydrochloride salt of cetirizine.

36. (Original) An amorphous form of dextrorotatory dihydrochloride salt of cetirizine, which is substantially free of crystalline forms of dextrorotatory dihydrochloride salt of cetirizine.

37. (Original) An amorphous form of dextrorotatory dihydrochloride salt of cetirizine characterized by an X-ray powder diffraction pattern substantially in accordance with Figure (3).

38. (Original) A pharmaceutical composition comprising a prophylactically or therapeutically effective amount of an amorphous form of a dextrorotatory dihydrochloride salt of cetirizine, and one or more pharmaceutically acceptable excipients.

39.(Original) The pharmaceutical composition of claim 38, which is substantially free of crystalline forms of dextrorotatory dihydrochloride salt of cetirizine.

40. (Original) A composition comprising dextrorotatory dihydrochloride salt of cetirizine as a solid, wherein at least 80% by weight of said dextrorotatory dihydrochloride salt of cetirizine is in an amorphous form.

41. (Original) The composition of claim 40, wherein at least 90% of said solid dextrorotatory dihydrochloride salt of cetirizine is in an amorphous form.

42. (Original) The composition of claim 40, wherein at least 95% of said solid dextrorotatory dihydrochloride salt of cetirizine is in an amorphous form.

43. (Original) The composition of claim 40, wherein at least 99% of said solid dextrorotatory dihydrochloride salt of cetirizine is in an amorphous form.

44. (Original) The composition of claim 40, which is substantially free of the crystalline forms of dextrorotatory dihydrochloride salt of cetirizine.

45. (Original) The composition of claim 40, wherein at most 1% of said solid dextrorotatory dihydrochloride salt of cetirizine is in a crystalline form.

46. (Original) The composition of claim 40, wherein at most 5% of said solid dextrorotatory dihydrochloride salt of cetirizine is in a crystalline form.

47. (Original) The composition of claim 40 having a moisture content ranging from about 0.3% to about 12% by KF method.

48. (Original) The composition of claim 40 having a moisture content ranging from about 1.5% to about 7.5% by KF method.

49. (Original) A process for the preparation of an amorphous form of dextrorotatory dihydrochloride salt of cetirizine, said process comprising:

a) dissolving a dextrorotatory dihydrochloride salt of cetirizine in a ketone containing solvent at about 25°C to about 40°C;

b) distilling said ketone-containing solvent below about 80°C under reduced pressure to obtain a residue and

c) drying said residue at a temperature below about 100°C to obtain the amorphous form of dextrorotatory dihydrochloride salt of cetirizine.

50. (Original) The process according to claim 49, wherein said ketone-containing solvent comprises water and a ketone selected from the group consisting of acetone, methyl ethyl ketone, acetone, methyl ethyl ketone, dimethyl ketone, 2-pentanone, and mixtures thereof.

51. (Original) The process according to claim 49, wherein said ketone-containing solvent

comprises water and acetone.

52. (Original) The process according to claim 49, wherein said dissolution step is carried out at from about 25°C to about 35°C.

53. (Original) The process according to claim 49, wherein said drying step is conducted at about 40°C to about 100°C.

54. (Original) The process according to claim 53, wherein said drying step is conducted at about 80°C to about 90°C.

55. (Original) The process according to claim 49, wherein said dextrorotatory dihydrochloride salt of cetirizine of step a) is crystalline.

56. (Original) The amorphous form of dextrorotatory dihydrochloride salt of cetirizine produced in accordance with the process of claim 49.

57. (Original) A pharmaceutical composition comprising i) a prophylactically or therapeutically effective amount of dextrorotatory dihydrochloride salt of cetirizine in a solid form produced by the process of claim 49 and ii) one or more pharmaceutically acceptable excipients.

58. (Original) The composition of claim 57, wherein said pharmaceutical composition is a solid dosage form for oral administration.

59. (Original) The composition of claim 58, wherein said solid dosage form is a tablet.

60. (Original) The composition of claim 57, having a moisture content ranging from about 0.3% to about 12% by KF method.

61. (Original) The composition of claim 57, having a moisture content ranging from about 1.5% to about 7.5% by KF method.

62. (Original) An amorphous form of levorotatory dihydrochloride salt of cetirizine.

63. (Original) An amorphous form of levorotatory dihydrochloride salt of cetirizine, which is substantially free of crystalline forms of levorotatory dihydrochloride salt of cetirizine.

64. (Original) An amorphous form of levorotatory dihydrochloride salt of cetirizine characterized by an X-ray powder diffraction pattern substantially in accordance with Figure (4).

65. (Original) A pharmaceutical composition comprising a prophylactically or therapeutically effective amount of an amorphous form of a levorotatory dihydrochloride salt of cetirizine and one or more pharmaceutically acceptable excipients.

66. (Original) The pharmaceutical composition of claim 65, which is substantially free of crystalline levorotatory dihydrochloride salt of cetirizine.

67. (Original) A composition comprising levorotatory dihydrochloride salt of cetirizine as a solid, wherein at least 80% by weight of said levorotatory dihydrochloride salt of cetirizine is in an amorphous form.

68. (Original) The composition of claim 67, wherein at least 90% of said solid levorotatory dihydrochloride salt of cetirizine is in an amorphous form.

69. (Original) The composition of claim 67, wherein at least 95% of said solid levorotatory dihydrochloride salt of cetirizine is in an amorphous form.

70. (Original) The composition of claim 67, wherein at least 99% of said solid levorotatory dihydrochloride salt of cetirizine is in an amorphous form.

71. (Original) The composition of claim 67, which is substantially free of the crystalline forms of levorotatory dihydrochloride salt of cetirizine.

72. (Original) The composition of claim 67, wherein at most 1% of said solid levorotatory dihydrochloride salt of cetirizine is in a crystalline form.

73. (Original) The composition of claim 67, wherein at most 5% of said solid levorotatory dihydrochloride salt of cetirizine is in a crystalline form.

74. (Original) The composition of claim 67 having a moisture content ranging from about 0.3% to about 12% by KF method.

75. (Original) The composition of claim 67 having a moisture content ranging from about 1.5% to about 7.5% by KF method.

76. (Original) A process for the preparation of an amorphous form of levorotatory dihydrochloride salt of cetirizine, said process comprising:

a) dissolving a levorotatory dihydrochloride salt of cetirizine in a ketone-containing solvent at about 25°C to about 40°C;

b) distilling said ketone-containing solvent below about 80°C under reduced pressure to obtain a residue; and

c) drying said residue at a temperature below about 100C to obtain the amorphous form of levorotatory dihydrochloride salt of cetirizine.

77. (Original) The process according to claim 76, wherein said ketone-containing solvent comprises water and a ketone selected from the group consisting of acetone, methyl ethyl ketone, acetone, methyl ethyl ketone, dimethyl ketone, 2-pentanone, and mixtures thereof.

78. (Original) The process according to claim 76, wherein said ketone-containing solvent comprises water and acetone.

79. (Original) The process according to claim 76, wherein said dissolution step is carried out at from about 25°C to about 35°C.

80. (Original) The process according to claim 76, wherein said drying step is conducted at about 40°C to about 100°C.

81. (Original) The process according to claim 76, wherein said drying step is conducted at about 80°C to about 90°C.

82. (Original) The process according to claim 76, wherein said levorotatory dihydrochloride sat of cetirizine is crystalline.

83. (Original) The amorphous form of levorotatory dihydrochloride salt of cetirizine produced in accordance with the process of claim 76.

84. (Original) A pharmaceutical composition comprising i) a prophylactically or therapeutically effective amount of levorotatory dihydrochloride salt of cetirizine in a solid form produced by the process of claim 76 and ii) one or more pharmaceutically acceptable excipients.

85. (Original) The composition of claim 84, wherein said pharmaceutical composition is a solid dosage form for oral administration.

86. (Original) The composition of claim 85, wherein said solid dosage form is a tablet.

87. (New) The pharmaceutical composition of claim 32, which is a solid dosage form for oral administration.

88. (New) The pharmaceutical composition of claim 87, wherein said solid dosage form is a tablet.